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26

STEPHANIE L. SEIDMAN, ESO.  
BROWN, MARTIN, HALLER & MCCLAIN  
1660 UNION STREET  
SAN DIEGO, CALIFORNIA 92101-2926

1812

DATE MAILED:

10/27/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

4/29/96

This application has been examined  Responsive to communication filed on 5/17/96  This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s). 8 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.      | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1.  Claims 53 to 63, 66 to 68, 70 to 96 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.

3.  Claims 79, 81, 85 are allowed.

4.  Claims 53 to 63, 66 to 68, 70 to 78, 80, 82 to 84, 86 to 92, 95, 96 are rejected.

5.  Claims 93, 94 are objected to.

6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.

7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8.  Formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).

12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14.  Other

Art Unit: 1812

1) Since this application is eligible for the transitional procedure of 37 C.F.R. § 1.129(a), and the fee set forth in 37 C.F.R. § 1.17(r) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. § 1.129(a).

2) Claims 53 to 63, 66 to 68 and 70 to 96 are pending in the instant application. Claims 53 to 61, 68 and 73 to 75 have been amended and claims 76 to 96 have been added as requested by Applicant in Paper Number 23, filed 29 April of 1996.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

5) Claim 75, which is being examined on its merits in the instant Office Action, has not been amended in accordance with 37 C.F.R. § 1.121. Specifically, the change from [an] to a is improper because "an" did not originally appear in this claim. The addition of "the plasmid" to material which is being deleted by amendment is highly improper. Applicant is required to cancel this claim in their next response and, if desired, present a new claim containing all of the limitations that were intended for this claim. Otherwise, if allowed, this claim can not be printed since it has not been properly amended during its prosecution.

Art Unit: 1812

6) Claims 93 and 94 are objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. See M.P.E.P. § 608.01(n). Accordingly, these claims not been further treated on the merits.

7) Claims 53 to 63, 66 to 68, 70 to 77, 86, 88 to 92, 95 and 96 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a nucleic acid encoding one of the subunits which is encoded by the biological material that was deposited as described in lines 10 to 14 on page 19 of the instant specification. The instant specification is not enabling for the production of a nucleic acid encoding less than the entire subunit of a human neuronal nicotinic acetylcholine receptor (nAChR) as encoded by one of the referenced deposits or for the production of less than the entire subunit encoded thereby. For example, the instant specification describes only one human alpha 2 nAChR subunit and that subunit is only described in the context of being encoded by clone HnAChR $\alpha$ 2. Neither the amino acid sequence or any other structural information has been provided about this protein. The specification does not disclose how this clone was made and does not identify those parts of the protein encoded thereby which are essential for its biological activity. In the absence of this information a practitioner would be incapable of producing a

Art Unit: 1812

human alpha 2 nAChR subunit other than that which is encoded by this clone.

8) Claims 54 to 57, 58 to 63, 66 to 68, 70, 72 to 74, 76, 77, 86 to 92 and 95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claims 53, 54 and 58 each recites an improper Markush group because the elements recited therein do not posses a common property which is mainly responsible for there function on the claimed relationship. These are three distinct proteins which can not be used interchangeably in the claimed invention. Claims 55 to 57, 59 to 63, 66 to 68, 70, 79 to 84, 86 to 92 and 95 are incorrect in so far as they depend from any of claims 53, 54 or 58 for this element. See M.P.E.P. 2173.05(h) .

8.2) Claims 55 and 56 are incorrect because there is no antecedent basis for the "receptor encoded by the nucleic acid of claim 53". The nucleic acid of claim 53 encodes a receptor subunit, not a receptor.

8.3) Claim 57 is incorrect be cause a nucleic acid, which **is** a material entity, can not hybridize to a nucleic acid sequence, which is nothing more than a property of a nucleic acid and is incapable of hybridizing to anything. This claim is also

Art Unit: 1812

incorrect because there is no antecedent basis for "a subunit of claim 53" in claim 53, which is drawn to a nucleic acid.

8.4) Claim 59 is incorrect because there is no antecedent basis for the plural term "nucleic acids" in claim 53. This claim, as well as claims 60 to 63, 66, 67 and 91 are incorrect because a claim must be directed to a single invention. These claims should be directed to "A cell" and not "Isolated cells".

8.5) Claims 67 and 70 are each incorrect because there is no antecedent basis for "the" human alpha 2, alpha 3 and beta 2 subunit. Claim 70 is also incorrect because there is no antecedent basis for "the alpha subunit".

8.6) Claim 68 is incorrect because there is no antecedent basis for "the" nicotinic acetylcholine receptor activity or for the plurality of "receptors" in the term "nicotine binding to the receptors. This claim is incorrect because of the double occurrence of the term "the electrophysiological response of the cells" at the end of this claim.

8.7) Claims 73, 74, 86 are vague and indefinite because the term "substantial homology" has no clear meaning in the art and it is not possible to determine what is encompassed and what is excluded by this term. The term "substantial" simply means not imaginary. The term "homology" indicates that the referenced item has an analogous structure or function relative to an item from a different organism. Claims 76 and 77 are indefinite in so

Art Unit: 1812

far as they depend from either of claims 73 or 74 for this element.

9) Claims 68 and 92 are rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. A claim to a method is not a further limitation of the cell of a claim from which it depends.

10) Claim 72 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 72 is drawn to a method which obviously can not further limit a nucleic acid which is the subject of claim 53 from which this claim depends.

11) Claims 55, 56, 76 to 78, 82 to 84 are rejected under 35 U.S.C. § 112, fourth paragraph, because a claim to a protein does not further limit a claim to a nucleic acid since these are chemically unrelated compounds. It is further noted that claims 55 and 56 are identical to one another.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Art Unit: 1812

12) Claim 80 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5,369,028. This is a double patenting rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13) Claims 55, 56, 76 to 78 and 82 to 84 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by the Whiting et al. publication (J. Neuroscience 8(9):3395-3404, Sep. 1988). The limitation "substantially pure" simply requires the recited compound to be found in any state of purity that is higher than occurs in nature. These claims, as written, are anticipated by noting more than a membrane preparation from any cell line or tissue which contains one of the disclosed receptor subunits. In the instant case Figure 5B on page 3400 of Whiting et al. described several sucrose gradient fractions which clearly meet all of the limitations of the pending claims.

14) Claims 53, 54, 57 to 63, 66, 67, 74, 89 and 91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim of U.S. Patent No. 5,369,028. Although the conflicting claims are not identical, they are not patentably distinct from each other

Art Unit: 1812

because the pending claims completely encompass the subject matter of the allowed claims. Allowance of the pending claims, therefore, would have the prohibited effect of extending the enforceable life of the patent claims beyond the statutorily set time period.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

15) The Declaration by Steven Bradley Ellis under 37 C.F.R. § 1.132 filed 13 May of 1996 is sufficient to overcome the rejection of the pending claims based upon the Boulter et al. publication.

16) Claims 79, 81, and 85 are allowable as written.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm at telephone number (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM. The fax phone number for this group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800